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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/807,506

02/27/1997

VICTOR SMIT

7392/71226

5096

42798

7590

05/24/2006

FITCH, EVEN, TABIN & FLANNERY

P. O. BOX 65973

WASHINGTON, DC 20035

EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/807,506

Applicant(s)

SMIT ET AL.

Examiner

Agnieszka Boesen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94-121, 123, 124 and 129-136 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 94-121, 123, 124 and 129-136 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Art Unit 1648. Claims 94-121, 123, 124 and 129-136 are pending.

In a telephone interview between Examiner Timothy Brown and Applicant's representative, Kendrew Colton on October 5, 2004, it was noted that the supplemental amendment filed January 15, 2003 was not considered in the subsequent Office action dated April 19, 2004. The Examiner indicated that a letter restarting the period for response would be mailed to Applicant, presumably with a supplemental Office action taking into consideration the amendment filed January 15, 2003.

Upon further consideration, the Final Office Action mailed on April 19, 2004 has been vacated in favor of the following restriction requirement. 37 CFR 1.142(a) indicates that a restriction requirement will normally be made before any action upon the merits; however, it may be made at any time before final action. In this case, the finality of the Office action dated April 19, 2004 is withdrawn and the action vacated. The Office recognizes that the instant application has been pending since February 27, 1997 and that a requirement for restriction between inventions was not made during earlier prosecution of this application. However, given the claimed subject matter and the reasoning set forth below, examination of the instant application requires Applicant to elect one invention. Any inconvenience is regretted.

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 94-111, 133, and 136, drawn to a method for quantitative structure function analysis on biologically active proteins or peptides.

Group II, claim 124, 129 and 132, drawn to a method for stimulating stem cell-replication.

Group III, claim 130, drawn to a method of gene therapy.

Group IV, claims 112, 115, 116-119, 120, 121, 123, and 131 drawn to a modified signal substance.

Group V, claims 113, 114, 115, 119, 131, 134, and 135 drawn to a modified signal substance being Zinc binding signal peptide.

The inventions listed as Groups I, II, III, IV, V, and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The asserted special technical feature shared by all of the claims is the gradual chemical modification of a protein or peptide for purposes of discovering new biological features of the protein or peptide. The specification teaches that the stepwise, gradually increasing modification of the peptide (by chemical reaction) allows sensitive identification of changes in biological activity associated with the structural modification (page 5, second full paragraph). The product claims, drawn to various proteins, hormones, factors, etc., contain a modification within or in such close proximity to a catalytic center (or Zinc binding center) such that it affects a biological or chemical feature.

Katre et al. (WO 88/01511) teaches the chemical modification of interleukin-2, whereby the biological activity of interleukin-2 is altered (see page 14, lines 20-30 and the claims).

Since Applicant's invention does not contribute a special technical feature when viewed over the prior art, they do not have a single inventive concept and thus the claims lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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The species are as follows:

Species for group I, Set 1, drawn to a method for quantitative structure function analysis research, wherein the step of monitoring the modification reaction is performed by:

- a) Electrophoresis
- b) Electrospray mass spectroscopy

Species for group I, Set 2, drawn to a method for quantitative structure function analysis research, wherein the substance to be modified is:

- c) Interleukins. If Applicant elects interleukins of the cytokine superfamily, Applicant is required to further elect **one** interleukin from IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8 and IL-10.
- d) Hematopoietic growth factors. If Applicant elects hematopoietic growth factors of the cytokine superfamily, Applicant is required to further elect one of GM-CSF and EPO.
- e) Tumor Necrosis Factor (TNF) of the cytokine superfamily
- f) IFN gamma of the cytokine superfamily
- g) Peptide and protein hormones
- h) Signal peptides and signal proteins
- i) Insulin
- j) Prolactin

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Species of group V, drawn to a modified signal substance containing modification within or in close proximity to a catalytic center:

- 1) protein or peptide hormone
- 2) growth factor, hematopoietic growth factor
- 3) interferon
- 4) interleukin
- 5) colony stimulating factor

Species of group VI, drawn to a modified signal substance being a Zinc binding signal peptide:

- 6) growth hormone
- 7) prolactin
- 8) insulin
- 9) cytokine acting on a receptor

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The following claim(s) are generic: 94, 100-109, 114-117, 120-124, 129-131, 133, and 136.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Because the special technical feature, which is the modified interleukin 2, is known, the remaining species lack unity of invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

May 19, 2006

Stacy B. Chen 5/19/2006

Stacy B. Chen
Primary Examiner